

REMARKS

Claims 1-19 and 21-26 are pending. No claims are amended herein. No new matter is added.

Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

Rejections under 35 U.S.C. § 112

The Examiner continues to object to the use of "substantially nugget-free" in Claim 1. Applicants submit that the skilled artisan would understand from the specification and general knowledge of a person of skill in the art that "substantially nugget-free" means that nuggets are not present or are present in an amount that is not readily visible. Accordingly, Applicants respectfully request withdrawal of this rejection.

Delespaul Does Not Anticipate Claims 1-11 and 25-26

Claims 1-11 and 25-26 stand rejected under 35 U.S.C. § 102(b) as anticipated by FR 2452879 to Delespaul et al. (hereinafter "Delespaul").

Applicants kindly remind the Examiner that *anticipation* under Section 102 can be found *only* if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

First, the Examiner is clearly not applying the correct legal standard for anticipation. In the Final Office Action, the Examiner found that:

It is agreed that Delespaul does not disclose a dried MPC, however, since Delespaul employs calcium depleted and heat treated concentrated milk, the cheese produced using the treated milk product, of Delespaul, will be substantially nugget free. In other words the end result of using the Delespaul product or reconstituting the dried MPC as presently claimed would be nugget free cheese. The whole emphasis of Delespaul is preparation of a cheese having a fine and homogenous texture. (please see paragraph 3 of page 7 of the official translation provided to you). Further, *it is noted that while Delespaul does not disclose a dried milk protein concentrate (MPC)*, in light of the open language of the present claims, i.e. "comprising", the claims are clearly open to the inclusion of

additional components including the calcium depleted, heat treated milk product disclosed by Delespaul. Page 9, paragraph 5(a) (emphasis added).

Thus, the Examiner *admits* that the Delespaul does not disclose a dried MPC, much less the processing of a HY-MPC as recited in Claims 1-11 and 25-26. Therefore, the anticipation rejections of Claims 1-11 and 25-26 in view of Delespaul are improper.

Delespaul *does not* disclose “dispersing in milk or water or other aqueous solutions a dried HY-MPC having at least 55% SNF as milk protein” as recited in Claim 1. Accordingly, Applicants request withdrawal of this rejection for at least this reason. Additionally, Applicants submit that Claims 2-9 are not anticipated by Delespaul, not only because they depend from Claim 1 but also on their own merit.

Delespaul *does not* disclose “adding a 10-100% calcium depleted HY-MPC to milk containing fat or any other aqueous solution used as the starting material” as recited in Claim 10. Accordingly, Applicants request withdrawal of this rejection for at least this reason.

Delespaul *does not* disclose “dispersing in milk a dried HY-MPC having at least 70% SNF as milk protein” as recited in Claim 11. Accordingly, Applicants request withdrawal of this rejection for at least this reason.

Delespaul fails to anticipate Claim 25 because it fails to teach a dried HY-MPC having 20-100% depletion of calcium. Additionally, Applicants submit that Claim 26 is not anticipated by Delespaul, not only because it depends from Claim 25 but also on its own merit.

Further, this deficiency is more than an obvious variation of Delespaul. Applicants submit that prior to the filing of the present application it was not known that it would be possible to prepare a *dried* calcium-depleted heat-treated MPC that could subsequently be dissolved and used to make cheese. In particular, heat denaturation of proteins is generally associated with the loss of solubility. The disclosure in the present application is an important advance as it provides a *dry* ingredient that can be brought to a cheese factory where there are no facilities to prepare retentates, or calcium-depleted retentates as required by the *Delespaul* method.

Applicants also again disagree with the Examiner’s finding that the cheese produced by Delespaul would inherently be substantially nugget free as presently claimed. As discussed above, Delespaul cannot solve the problem of nugget formation associated with the processing of dried MPC because Delespaul *does not* disclose processing dried MPC. Delespaul does not

teach or suggest making cheese using a *dried* MPC, therefore it cannot be inherent that a cheese made by such a process would be substantially nugget free. Thus, Applicants submit that the Examiner has not met the burden to show that this feature *must necessarily* flow from the teachings of Delespaul, as required to support a finding of inherency. Accordingly, Applicants respectfully request withdrawal of this rejection.

Further, these deficiencies are more than obvious variations of Delespaul because Delespaul does not disclose forming dried HY-MPC or even recognize the problem of nugget formation when using dried MPC, much less suggest a way to solve the problem or the desirability of making cheese using dried HY-MPC.

Rejections under 35 U.S.C. § 103(a)

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); (“the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]”, *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmasiem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Claims 7 and 12-19, and 21-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Delespaul in view of WO 01/41578 to Bhaskar et al. (hereinafter “Bhaskar”).

The Examiner found that "Bhaskar does not have to teach heat treatment because Delespaul teaches that limitation." Applicants submit that the Examiner is impermissibly combining unrelated features from Delespaul and Bhaskar and that there is no reason for the skilled artisan to combine the heat treatment process of Delespaul, where the heat treatment is applied as part of a cheese making process, with the MPC making process of Bhaskar. Further, the combination does not teach all of the features of the claims.

Delespaul discloses a heat treatment step in the context of improving the texture of cheeses *produced by ultrafiltration*. Importantly, the heat treatment in Delespaul is applied to the retentate or liquid starting material. As discussed above, Delespaul fails to disclose drying to form MPC. There is no teaching or suggestion of heat treatment in Delespaul that would be useful in forming an MPC.

Bhaskar focuses on providing a method of making a dried MPC for use in a *conventional* cheese making process involving separation of casein and whey. The process disclosed in Bhaskar focuses on preparation of calcium depleted MPC. Bhaskar fails to disclose a heat treatment prior to drying. Because the heat treatment step in Delespaul is unrelated to forming an MPC product, there is no reason to combine the heat treatment step disclosed in Delespaul with the process disclosed in Bhaskar. Further, the skilled artisan would not be motivated to conduct a heat treatment step in Bhaskar prior to drying because it would be well understood that the denatured proteins would make reconstitution difficult and thus would impair the function of the MPC.

With regards to Claim 7, the reasoning for the combination proposed by the Examiner does not make sense. In the rejection, the MPC of Bhaskar is substituted into the process of Delespaul. However, there is no reason to use the heat treatment of Delespaul in the process of Bhaskar. The heat treatment of Delesapaul is done on the liquid material that is to be ultrafiltered or on the retentate. This provides no reason or teaching to do any heat treatment in Bhaskar. Accordingly, there is no reason for the skilled artisan to do any heat treatment in the process of Bhaskar because Bhaskar is focused on making a dried MPC, not on an ultrafiltration process for cheese making. There is also no reason or suggestion to dry the heat treated product of Delespaul because it is used directly to make cheese. The skilled artisan would have no reason to add a drying step.

The combination also fails to disclose the features of Claim 7. As discussed above, Delepaul *does not* disclose “dispersing in milk or water or other aqueous solutions a dried HY-MPC having at least 55% SNF as milk protein” as recited in Claim 1. Claim 7 further recites “wherein the HY-MPC has been prepared using heating for 4-15 minutes at greater than 100°C”. Bhaskar fails to make up for the deficiencies of Delepaul as Bhaskar fails to disclose any heat treatment. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

The combination suggested by the Examiner also fails to teach the features recited in Claims 12 and 18. Claims 12 and 18 are both directed to making dried products, such as MPC. Delepaul is focused on a heat treatment step in the context of methods for improving the texture of cheeses using ultrafiltration. Delepaul is not at all concerned with forming an MPC. As discussed above, there is no reason to use any heat treatment step in the process of Bhaskar, much less the heat treatment of Delepaul, which is used in a cheese making process, not a process for making MPC. Accordingly, Applicants submit that the combination is improper and respectfully request withdrawal of the rejections of Claims 12 and 18.

Further, Claim 12 recites in part “heating the solution at a temperature, for a time sufficient to allow denaturation of whey proteins and interaction with casein”. Claim 18 recites in part “denaturing whey proteins in the calcium depleted product by heating the solution at pH 6.0-7.0 at a temperature, and for a time sufficient to allow denaturation of whey proteins, or by applying an ultra high pressure treatment”. The heating step of Delepaul fails to disclose such heat treatment steps or that it would be advantageous to use such heat treatment steps. Bhaskar also fails to make up for this deficiency. Accordingly, Applicants respectfully request withdrawal of Claims 12 and 18 and their dependents for at least this reason as well.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other

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broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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